Database

MITO-MANGO

USER MANUAL

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Study Sponsor	*Author*
	LUCA CLIVIO AMM S.I. PANDORA RBB PANDORA Tel. 8330 Fax

TABLE OF CONTENTS

* Cover Page
* Introduction
* Deployment
* Access to the System
 - Page 1: panelProvetta
* License

INTRODUCTION

In the field of the data sharing infrastructures, in the last 15 years most of the clinical trials have been handled by home made web based remote data entry engines or even commercial ones but with a common web based centralized view, but this approach has evidenced some limitations such as the need for a permanent "fast enough" network connection (impossibility of working offline), the need for a "always well configured" web browser, the problem that it is not so easy to keep a local copy of the Database without having to deal with technical & security issues and it is not so easy to deal with "asynchronous tasks" to be committed to the Central Servers (typical task for "omics" data querying as well as for the imaging data analysis such as the MRI), and of course this approach involves the needing for an unlimited trust in the unique Central Repository holders, and this is often a problem that prevents groups to share some data.

On the other side, the current evolution of the data management related tasks in the field of "-omics" and imaging data analysis research involves a number of research project in the field of bioinformatics and data integration challenges between various data sources, ranging from cell lines or tissues data banks to clinical trials handling to genomics as well as proteomics experiments. Moreover the growing number of instrumental analysis for diagnostic or prognostic purposes is making become even more important the data integration between very heterogeneous data sources. As a matter of example, clinical data usually take a very little space if compared with high resolution images coming from PET, CT, MRI or even Micro-arrays, but on the other hand the current laws about the data protection (privacy laws) force a complete audit trail about any data modification in a clinical database, making the dimensions grow.

An activity such as querying an imaging database involves a research in new technologies for storing and retrieving data from a network of federated databases.

Last but not least, the enormous amount of "never published" data coming from clinical trials as well as from "-omics" experiments and imaging data that are kept private for the lack of statistical significance or due to a negative (i.e. unwanted) result could be an interesting treasure to be shared in a trust based network. About what to share a particular attention must be paid to let groups decide what to share and what to kept private when dealing with not still published data or in any case not necessary to be shared data, but a "do ut des" mechanism is important to encourage groups share more data than what they usually do, for instance for the purpose of having access to more data coming from others in a balanced way.

Implementation

This system is a FDA cfr21 part 11 open source "Push-based Peer to Peer Database" engine for asynchronous data and software update, with a "all I need" local repository for data storage and analysis and the opportunity of using the shared network storages and computation facilities only when needed. Completely decentralized, without any former server used for collecting all the data, this software is able to deal with distributed and partially/fully redunded data in all the partners commodity computers.

This system has been developed as a general purpose but oriented to bioinformatics and data sharing engine for clinical trials peer to peer network build on an open source peer to peer database to be used for both storing and handling data from various sources (biobanks, clinical trials, imaging and genomic experiments) for research networks, covering all the technical and regulatory aspect.

This software has been recently audited by an E.C.R.I.N. (European Clinical Research Infrastructure Network) commission, that has certified is as a valuable system for managing clinical trials.

This kind of database covers several aspects: every "User Node" can work either independently or even in collaboration with others for sharing data, obtain performance or storage clustering from the network and asynchronous tasks can be passed to remote nodes and results can be obtained in a subsequent time, upon a new connection. The system is scalable because nodes can be added to the network at any time, offering services (something like "web services") to the network or obtaining shared data, and in case of a node failure the redundancy of the network allows to easily obtain a new copy of the lost shared data.

DEPLOYMENT

The package is provided for download in a dedicated web page, and is available for Windows, Linux, Mac OSX.

Download eCRF - Executable version for MS Windows

Version intended to be used with MS Windows (tested with Windows XP, Vista, 7, 8, 8.1).

It's a unique executable file (.exe) to be saved tipically in the Desktop folder. In order to obtain the program, click on the first provided link.

If you use Internet Explorer, choose RUN whenever possible, not SAVE. Now a box will open down, which says that the downloaded program may damage your pc. Click on ACTIONS and select "RUN IN ANY CASE". Choose then "EXTRACT" in the next box. Now a new folder will be automatically created on the Desktop, whose name is "MITO-MANGO_database". An icon of a sailer will be created sideways. They must neither be deleted nor separated.

If a notice appears, which says that Windows Firewall blocked some functionalities of the program, choose "allow access".

If you use Firefox a message will appear: Opening MITO-MANGO.exe. You have to select "Save file".

A new window will appear at the top of the page, on the right: MITO-MANGO.exe. This means that the package has been saved in your download folder: when this message appears, go to your download folder, cut MITO-MANGO.exe and paste it on your desktop.

If you use Chrome a bar will appear at the bottom of the page which shows the download of MITO-MANGO.exe. Once downloaded MITO-MANGO.exe, a warning message will appear on the bar: it says MITO-MANGO.exe could be dangerous. Click the arrow next to the message and select "Keep".

Then go to your download folder, cut MITO-MANGO.exe and paste it on your desktop.

Download eCRF - Executable version for MS Windows, with a fake file extension (.hb)

Version intended to be used with MS Windows. This file should be downloaded if for institution policy the direct download of a executable file is blocked.

Once downloaded and moved to the Desktop this file it is sufficient to rename it from MITO-MANGO.hb to MITO-MANGO.exe (by right clicking on the file and choosing "rename" in the context menu).

Download eCRF - Compressed version for MS Windows

Version to be used in case of network protection software that should block the download of the executable file above. Once downloaded, this compressed file should be extracted obtaining the executable file descripted above.

Download eCRF - Executable version for Linux

Version intended to be used with Ubuntu Linux (tested with Ubuntu Linux 10.10 to 14.10).

To work properly this software necessarily requires the installation of the packages 'python-wxgtk2.8' (mandatory), 'abiword' (optional), 'pspp' (optional), 'gnumeric' (optional), all already included in the standard Ubuntu distribution but not installed by default (to install them simply write in the Terminal (Menu Applications -> Accessories -> Terminal): "sudo apt-get install python-wxgtk2.8 abiword pspp gnumeric" (without double quotes, then press the Enter key, confirm the download requests and at the end close the Terminal).

Like the Windows version the downloaded file must be moved in the Desktop folder or in another folder the user has access (typically the Documents folder). Once downloaded the files the access rights must be changed to make it executable. Right click the file, choose the item "Properties", then open the panel "Permissions", enable the checkbox "allow the execution of the file as a program".

To execute the file click twice on it (a dialog box will appear with the options "Show/Execute", choose "Execute"), and at the first startup a folder named "MITO-MANGO_database" will be automatically created in the same location. This folder should never be deleted (as well as the downloaded ".sh" file) because contains all the data.

Download eCRF - Compressed executable version for Apple Mac OS X

Version intended to be used with Apple Mac OS X (tested with Leopard, Snow Leopard, Lion, Mountain Lion).

Like the Windows version the downloaded file must be moved in the Desktop folder or in another folder the user has access (typically the Documents folder).

To execute the file click twice on it, and at the first startup a folder named "MITO-MANGO_database" will be automatically created in the same location. This folder should never be deleted (as well as the downloaded ".command" file) because it contains all the data.

If the system is Mountain Lion and the application doesn't work it is necessary to install the package wxPython from this link: Scarica wxPython. Once downloaded, the file has to be executed clicking twice on it. A window will open, which contains the package (icon package-shaped): it has to be clicked twice, too.

If, after the double click on the package, Mac answers with an error such as ”damaged Package”, the problem depends actually on the firewall GateKeeper. In this case it is necessary to open a terminal and write:

sudo installer -pkg /Volumes/wxPython2.8-osx-unicode-2.8.12.1-universal-py2.7/wxPython2.8-osx-unicode-universal-py2.7.pkg -target /

In this way the package will be properly deployed.

ACCESS TO THE SYSTEM

Regardless to the installation mode previously choice, the file to run the HB system is always the downloaded executable MITO-MANGO.

After a while, the system will show the login page.

Please insert Username, Password and "Cypher key", provided you by e-mail at the study activation time. The username and password are personal for each user. Each user must access the system with her/his credentials.

The first access could take a few minutes.

If the credentials are correct you can enter the database system and the "search page" will appear.

Every time that the system detects an internet connection it will synchronize data automatically. This process has been intentionally kept slow in order not to overflow your computer with peaks of income data from other connected computers. To optimize this "protective" feature of this software you need to have HB connected as often as possible. This can be easily achieved in two ways: 1) when you have finished to update your data please exit the eCRF (see "How to exit the eCRF") but not exit the Database (see "How to exit the Database") 2) whenever your computer is connected to internet please remember to open up HB even if you do not need to enter data (in this case you do not even need to enter username and password) and leave it on.

You could verify the connection to synchronize data through the message "p2p connected" that appears on the status bar at the bottom left side of the screen.

PASSWORD

According to the current laws, at least every 90 days you have to to change your password, click on "Data management" and then select on the dropdown menu the option "Change user password". If you want you can change your password also at the first access.

The system will ask you to double enter the new password.

Only for Windows" users

If any message do not appear (after 10-20 seconds) when you open HB, you could iconify the HB"s window to verify the possible presence of an Internet Explorer authentication request.

Please, insert the network credentials you use daily to connect to internet.

NEW RECORD

Before starting to add a new record, please check the status bar at the bottom of the page. Please, remind that you can freely add or update records, but time to time the system should be able to access the internet.

If you want to add a new record, please click on "new record" at the left bottom of the "search page".

After a few second you will see the first data entry form. After having fullfilled all the data, please click on "Save" or "Save and Exit".

Once at least one record has been added, the possible activities are:

to list all records you have access, click on button find in the "search page";

to do a more focused search, fullfill any available search parameters and click on find;

if you check the box "tolerance" you can do an "approximate" search.

Select the code of the record that you would like to view and with double click on the code you see records itself.

HOW TO LEAVE A RECORD

You can exit a page with the button "save and exit" or "quit, don"t save":

if you click on "Quit, don"t save" and confirm the choice the eCRF will be closed and the data will be not saved (all the pages);

if you click on "Save and exit" and confirm the choice the eCRF will be closed and the data will be saved (al the pages).

SAVE AND DELETE OPTIONS

"delete record": this option is disabled, it is available only for the Coordinating Data Centre staff.

"save": this option saves the data and you can continue to work on the same CRF"s page.

HOW TO EXIT THE DATABASE

click on "exit" at the bottom on the right side of the "main page" to come back to the login page;

click on "activity" and select "exit" from the dropdown menu;

Please, never click on "X" at the top right side, you will lose all data not previously saved.

ASSISTANCE FOR e-CRF COMPILATION

The HB Database has internal controls to assist users during the eCRF compilation process. There are three types of controls:

1. Check congruence (between fields)

2. Check data format - alert if the inserted date is not possible (e.g. 55/55/5555)

3. Check for consecutive dates - alert if two dates (eg. date of consent and randomization date) are not consecutive

These internal checks can only produce alerts; they cannot block the data compilation.

When the alerts appears:

When you select the botton "Save" a window will show you a list of the possible errors or data that need you attention and revision.

The alert window permits three options:

1. Cancel - if you click on cancel the window disappered and the user can continue to complete the CRFs.

2. OK - with this option the user can take note the alert and flag them as acknowledgement.

3. Export - if you want to postpone the changes, click on export. In any case the user should flag the alerts for acknowledgement.

OTHER DATABASE FEATURES

Export search results

Pressing the button export search results you can export the list of records selected according to your searching criteria to an excel file (.xls).

Drop-down menu

Please note that in the e-CRF pages there are two types of dropdown menu: One type is "closed" as you cannot add any further options (e. g. field). The other type is "opened" as you can add to the specified list a new option (e. g. field).

Monitoring check

The check box called "Monitoring check", if present, may be found at the end of each e-CRF page, is for monitor(s)use only.

Once the study monitor clicks on this box, the investigator/data manager can view the page in "read only" mode. No change will then be possible.

Data extraction mode and Data analysis options

In the dropdown menu "Data management", at the top of the "main page", you can see two options, "Data extraction mode" and "Data analysis". Both these two options are disabled because are for the Coordinating Data Centre staff use only.

Audit trail

Once you are inside into a CRF of a record in the menu "Data Management" at the top of the page you can find the option "Audit Trail" that reports all the history of data changes (insert/modifications) for that record. This option is available only inside a CRF record.

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Written by

(sign) _____ (sign) _____ Date 30/3/2015

Last revised by

(sign) _____ (sign) _____ Date _____

Approved by

(sign) _____ (sign) _____ Date _____

MITO-MANGO

Progressivo

Num. Provetta

Tipo

Data di arrivo

Codice Frigorifero

Codice Rack

Codice Scatola

MITO-MANGO

Progressivo group_shorkayde

Num. Provetta p01_num_prov

Tipo p01_tipo {"","Plasma","Sangue"}

Data di arrivo p01_data_di_arri

Codice Frigorifero p01_codi_frig

Codice Rack p01_codi_rack

Codice Scatola p01_codi_scat

p01_01	p01_02	p01_03	p01_04	p01_05	p01_06	p01_07	p01_08	p01_09
p01_10	p01_11	p01_12	p01_13	p01_14	p01_15	p01_16	p01_17	p01_18
p01_19	p01_20	p01_21	p01_22	p01_23	p01_24	p01_25	p01_26	p01_27
p01_28	p01_29	p01_30	p01_31	p01_32	p01_33	p01_34	p01_35	p01_36
p01_37	p01_38	p01_39	p01_40	p01_41	p01_42	p01_43	p01_44	p01_45
p01_46	p01_47	p01_48	p01_49	p01_50	p01_51	p01_52	p01_53	p01_54
p01_55	p01_56	p01_57	p01_58	p01_59	p01_60	p01_61	p01_62	p01_63
p01_64	p01_65	p01_66	p01_67	p01_68	p01_69	p01_70	p01_71	p01_72
p01_73	p01_74	p01_75	p01_76	p01_77	p01_78	p01_79	p01_80	p01_81
p01_82	p01_83	p01_84	p01_85	p01_86	p01_87	p01_88	p01_89	p01_90

Study

MITO-MANGO

DATA STRUCTURE

EudraCT Number: _____

Last update 30/03/2015

Study Sponsor	***Author***
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TABLE OF CONTENTS

* Cover Page
* Document Objective
* Document Content
* General information
 - Page 1: panelProvetta

DOCUMENT OBJECTIVE

This document supplies a definition of the characteristics of all the variables contained in the MITO-MANGO study electronic CRF.

Document Content

The document consists in a series of tables containing:
1. Detailed information on the variables contained in each CRF, divided by CRF section.
2. The single re-coding options for each re-coded variable, listed in alphabetic order.

Detailed variables informations:
- Variable name: as it appears in the Heavybase database
- Variable label: as it appears on the e-CRF page
- Variable description: a short text describing the variable, may be identical or different from the label
- Variable format: which can be either text with its associated length or Date
- Field type: for a detailed description of this column please see the general information section below
- Variables recoding information:
  . Re-coded name: name of the re-coded variable
  . Re-coded format: which can be text, numeric or date
  . Re-coded code: the name of the recoding table associated to the specific variable
- Variable location (CRF page)

General variables informations:

* Trialcode is the computer-generated patient code. The Trialcode consists in:
- An initial three letters pathology code
- A serial number (usually 1 digit) of the trial in the same pathology
- A short centre code (usually 3 digits)
- A progressive patient code within each centre
- A single digit alphanumeric char consisting in a checksum of the other chars
- A single digit random alphanumeric char.

Format example: "MPM1 0001-001 PX"

** The variable names are formed by a maximum of 32 features, they start with a letter or underscore and do not contain spaces.*
* The variable formats of each date variable is dd/mm/yyyy and are nominated "Date"

* Main layout types for Variables:
- TB (text box) free text
- DC (drop down menu closed) the user cannot add any further options
- DO (drop down menu open) the user can add to the pre-specified list a new option
- CB (check box)

Cover (Patient search page)

Variable	*Description*	*Format*	*Type*	*Re-coded name*	*Re-coded format*	*Re-coded code*	*Page*
group_shortcode		$255	TB	group_shortcode			Tutte
key		#3	TB	key			Tutte
p01_num_prov		$255	TB	p01_num_prov			Tutte
p01_tipo		$6	DC	p01_tipo_cod	F1	P01_TIPO	Tutte
p01_data_di_arri		date	DATE	p01_data_di_arri	Date		Tutte
p01_codi_frig		$255	TB	p01_codi_frig			Tutte
p01_codi_rack		$255	TB	p01_codi_rack			Tutte
p01_codi_scat		$255	TB	p01_codi_scat			Tutte

panelProvetta

Variable	Description	Label	Format	Type	Re-coded name	Re-coded format	Re-coded code	Page
group_shortcode		Progressivo	$255	TB	group_shortcode			1
key		Progressivo	#3	TB	key			1
p01_num_prov		Data di arrivo	$255	TB	p01_num_prov			1
p01_tipo		Data di arrivo	$6	DC	p01_tipo_cod	F1	P01_TIPO	1
p01_data_di_arri		Data di arrivo	date	DATE	p01_data_di_arri	Date		1
p01_codi_frig		Codice Scatola	$255	TB	p01_codi_frig			1
p01_codi_rack		Codice Scatola	$255	TB	p01_codi_rack			1
p01_codi_scat		Codice Scatola	$255	TB	p01_codi_scat			1
p01_01		01	$1	CB	p01_01			1
p01_02		02	$1	CB	p01_02			1
p01_03		03	$1	CB	p01_03			1
p01_04		04	$1	CB	p01_04			1
p01_05		05	$1	CB	p01_05			1
p01_06		06	$1	CB	p01_06			1
p01_07		07	$1	CB	p01_07			1
p01_08		08	$1	CB	p01_08			1
p01_09		09	$1	CB	p01_09			1
p01_10		10	$1	CB	p01_10			1
p01_11		11	$1	CB	p01_11			1
p01_12		12	$1	CB	p01_12			1
p01_13		13	$1	CB	p01_13			1
p01_14		14	$1	CB	p01_14			1
p01_15		15	$1	CB	p01_15			1
p01_16		16	$1	CB	p01_16			1
p01_17		17	$1	CB	p01_17			1
p01_18		18	$1	CB	p01_18			1
p01_19		19	$1	CB	p01_19			1
p01_20		20	$1	CB	p01_20			1
p01_21		21	$1	CB	p01_21			1
p01_22		22	$1	CB	p01_22			1
p01_23		23	$1	CB	p01_23			1
p01_24		24	$1	CB	p01_24			1
p01_25		25	$1	CB	p01_25			1
p01_26		26	$1	CB	p01_26			1
p01_27		27	$1	CB	p01_27			1
p01_28		28	$1	CB	p01_28			1
p01_29		29	$1	CB	p01_29			1
p01_30		30	$1	CB	p01_30			1
p01_31		31	$1	CB	p01_31			1
p01_32		32	$1	CB	p01_32			1
p01_33		33	$1	CB	p01_33			1
p01_34		34	$1	CB	p01_34			1
p01_35		35	$1	CB	p01_35			1
p01_36		36	$1	CB	p01_36			1
p01_37		37	$1	CB	p01_37			1
p01_38		38	$1	CB	p01_38			1
p01_39		39	$1	CB	p01_39			1

p01_40		40	$1	CB	p01_40			1
p01_41		41	$1	CB	p01_41			1
p01_42		42	$1	CB	p01_42			1
p01_43		43	$1	CB	p01_43			1
p01_44		44	$1	CB	p01_44			1
p01_45		45	$1	CB	p01_45			1
p01_46		46	$1	CB	p01_46			1
p01_47		47	$1	CB	p01_47			1
p01_48		48	$1	CB	p01_48			1
p01_49		49	$1	CB	p01_49			1
p01_50		50	$1	CB	p01_50			1
p01_51		51	$1	CB	p01_51			1
p01_52		52	$1	CB	p01_52			1
p01_53		53	$1	CB	p01_53			1
p01_54		54	$1	CB	p01_54			1
p01_55		55	$1	CB	p01_55			1
p01_56		56	$1	CB	p01_56			1
p01_57		57	$1	CB	p01_57			1
p01_58		58	$1	CB	p01_58			1
p01_59		59	$1	CB	p01_59			1
p01_60		60	$1	CB	p01_60			1
p01_61		61	$1	CB	p01_61			1
p01_62		62	$1	CB	p01_62			1
p01_63		63	$1	CB	p01_63			1
p01_64		64	$1	CB	p01_64			1
p01_65		65	$1	CB	p01_65			1
p01_66		66	$1	CB	p01_66			1
p01_67		67	$1	CB	p01_67			1
p01_68		68	$1	CB	p01_68			1
p01_69		69	$1	CB	p01_69			1
p01_70		70	$1	CB	p01_70			1
p01_71		71	$1	CB	p01_71			1
p01_72		72	$1	CB	p01_72			1
p01_73		73	$1	CB	p01_73			1
p01_74		74	$1	CB	p01_74			1
p01_75		75	$1	CB	p01_75			1
p01_76		76	$1	CB	p01_76			1
p01_77		77	$1	CB	p01_77			1
p01_78		78	$1	CB	p01_78			1
p01_79		79	$1	CB	p01_79			1
p01_80		80	$1	CB	p01_80			1
p01_81		81	$1	CB	p01_81			1
p01_82		82	$1	CB	p01_82			1
p01_83		83	$1	CB	p01_83			1
p01_84		84	$1	CB	p01_84			1
p01_85		85	$1	CB	p01_85			1
p01_86		86	$1	CB	p01_86			1
p01_87		87	$1	CB	p01_87			1
p01_88		88	$1	CB	p01_88			1
p01_89		89	$1	CB	p01_89			1
p01_90		90	$1	CB	p01_90			1

List of Closed drop-down menu (DC)

p01_tipo
Plasma
Sangue

p01_tipo (see p01_tipo)

List of drop-down menu opened (DO)

List of Formats

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